

## REMARKS/ARGUMENTS

Claims 1-30 remain in this application. No claims have been cancelled or amended.

The Examiner has rejected claims 1-22 and 26-30 under 35 U.S.C. 103(a) as being unpatentable over United States Patent No. 5,213,811 to Frisbee et al., in view of United States Patent No. 4,663,318 to Davis.

Specifically, the Examiner states that Frisbee et al. discloses the various elements found in the claims of the present invention, but not the use of galantamine as an active agent. Applicants respectfully disagree with the Examiner's conclusions regarding the Frisbee et al. disclosure and traverse the rejection on these grounds. For example, Applicants note that the Frisbee et al. formulation requires a sustained-release coating of at least three polymers (Col. 1, lines 38-51) among which is ethyl cellulose. There is no teaching or suggestion in Frisbee et al. that ethyl cellulose, alone, as claimed in the instant claim 11, can accomplish sustained release of galantamine. The necessity for three polymers in Frisbee et al. diverges from and teaches away from the present invention that employs a single polymer.

The Court of Appeals for the Federal Circuit repeatedly has stated that it is impermissible within the framework of a Section 103 rejection to pick and choose from any one reference only so much of it as will support a given position to the exclusion of other parts necessary for the full appreciation of what the reference fairly suggests to one of ordinary skill in the art. One cannot consider a reference in less than the entirety, *i.e.*, disregard disclosures in the reference that diverge from and teach away from the invention. Specifically, the Federal Circuit, in *In re Hedges*, 228 USPQ 685, 687 (Fed. Cir. 1986) stated:

We agree with Hedges that the prior art as a whole must be considered. The teachings are to be viewed as they would have been viewed by one of ordinary skill. *Kimberly-Clark v. Johnson & Johnson*, 745 F.2d 1437, 1454, 223 USPQ 603, 614 (Fed. Cir. 1984); *In re Mercier*, 515 F.2d 161, 1165, 185 USPQ 774, 778 (CCPA 1975). "It is impermissible within the framework of a Section 103 rejection to pick and choose from any one reference only so much of it as will support a given position to the exclusion

of other parts necessary to the full appreciation of what the reference fairly suggests to one of ordinary skill in the art".  
*In re Wesslau*, 353 F.2d at 241, 147 USPQ at 393.

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The Federal Circuit in *W.L. Gore & Associates v. Garlock, Inc.*, 220 USPQ 303 (Fed. Cir. 1983), in relation to the obviousness issue, recited, at page 311, "the district court erred . . . in considering the references in less than their entireties, *i.e.*, in disregarding disclosures in the references that diverge from and teach away from the invention at hand." (emphasis added). Thus, the Examiner cannot ignore the teaching in Frisbee et al. of a necessity for three polymers in the sustained-release coating, which teaching diverges from the instantly claimed invention.

Furthermore, there are numerous claim elements of the instant claims that have not been addressed by the Examiner and are not found in the art cited by the Examiner. By way of example, the Examiner's attention is drawn to claim 15 of the instant application.

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The Examiner has also rejected claims 23-25 under 35 U.S.C. 103(a) as being unpatentable over United States Patent No. 5,213,811 to Frisbee et al., in view of United States Patent No. 4,663,318 to Davis and further in view of WO 98/22072 to Willson. For the reasons above relating to the Examiner's rejection of claims 1-22 and 26-30, and for the additional reasons below, Applicants also traverse the rejection of claims 26-30 over the cited art.

As with the rejection over claims 1-22 and 26-30, the Examiner has not addressed all the elements of claims 23-25 in his rejection. By way of example, none of the art cited by the Examiner teaches or suggests packaging adapted for treatment of acetylcholine-esterase-inhibitor-tolerant patients as claimed in claim 25.

Finally, The Examiner has stated in relation to both claim rejections that the burden is shifted to Applicants to show non-obviousness, and the Examiner invited Applicants to provide evidence of unexpected results with the present invention. Accordingly, and in order to move the present application to allowance without conceding the correctness of the Examiner's rejections, Applicants have submitted herewith a Declaration Under 37 C.F.R. § 1.132 of Luc Truyen, M.D. Ph.D. ("Truyen Decl.")

As Dr. Truyen's declaration shows, on the basis of several clinical trials, Applicants surprisingly have discovered that use of the instantly claimed galantamine controlled-release ("CR") formulation results in an unexpected reduction in nausea and vomiting as compared to the commercially available immediate-release ("IR") galantamine formulation, and that, in the aggregate, this reduction is not tied to a reduction in the maximum blood plasma concentration as would be expected, but instead, is tied to the rate of rise of blood plasma concentration. Truyen Decl. ¶¶ 6, 13, 14. These unexpected results rebut any *prima facie* case of obviousness, as nausea and dizziness are significant side effects for galantamine. Truyen Decl. ¶ 9. Applicants therefore respectfully request that the Examiner withdraw the outstanding rejections under 35 U.S.C. 103(a).

#### Conclusion

For all of the reasons above, claims 1 - 30 are believed to be in condition for allowance, ~~early notice of which would be appreciated. If the Examiner does not agree~~ that all claims are allowable, then a telephonic or in-person interview is respectfully requested to discuss any remaining issues and accelerate the eventual allowance of this application.

No fee is believed to be due with this response other than the fee for the accompanying petition for extension of time . Authorization is hereby given to charge all required fees to Johnson & Johnson Deposit Account No. 10-0750/ORT-1375/MBZ.

Respectfully submitted,

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